

Amendments to the Drawings:

The attached sheet of drawings includes changes to Fig. 18.

The sheet, which includes Fig. 18 and 19, replaces the original sheet including Fig. 18 and 19. In Fig 18, reference character for shaft, which was previously shown as "44" is sought to be deleted and reference character - numeral 5 showing shaft is sought to be added at the place of reference character - numeral "44"

Attachment : one replacement sheet .

Remarks/Arguments

Claims 13-22 and 24-27 were examined in the outstanding final office action mailed on 03/15/2010 (hereafter "Outstanding Office Action"). All claims were rejected. By virtue of this paper, claims 1-12 , 19, 24-27 are sought to be cancelled, claims 13,14,16,17,20,21 are sought to be amended, claims 15,18,22 are sought to be previously presented and claims 30-37 are new .Claims 23, 28 and 29 are sought to be withdrawn and currently amended to further clarify applicant's invention and to include all the limitations of generic claim 13 to allow rejoinder of these claims The amendments, cancellation and additions are believed not to introduce new matter, and their entry is respectfully requested. The cancellations and amendments are made without prejudice or disclaimer. Claims 13-18,20-22,23 and 28-37 are respectfully presented for consideration further in view of the below remarks.

Elections/ Restriction

Claim of Group II 23 is withdrawn and presently amended to further clarify applicant's invention and to include all the limitations of generic claim 1 to allow rejoinder of these claim. Claims of Group III 28,29 are withdrawn and presently amended to further clarify applicant's invention and to include all the limitations of generic claim 1 to allow rejoinder of these claims..Amendments are fully supported by specification and figures as originally filed. No new matter is believed or intended to be introduced by these amendments. As claim of Group II, 23 and Claims of Group III 28,29 are withdrawn and presently amended (See MPEP 714, permitting amendments to withdrawn claims) to include all the limitations of elected generic claim 1, applicant respectfully respect withdrawal of Election/ Restriction requirements and rejoin the claims of Group II and Group III.

Drawings

Applicant thanks examiner for accepting drawings and withdrawing objections. Regarding objection for reference character "44" , replacement sheet of drawings is attached with this paper .In Fig 18, reference character for shaft, which was previously by mistake shown as "44" is sought to be deleted and reference character - numeral 5 showing shaft is sought to be added at the place of reference character -numeral "44". The amendments to the drawings are believed not to introduce new matter and their entry is respectfully requested. Withdrawal of the objections with respect to Drawings is respectfully requested.

Specification

A substitute specification and abstract in proper grammar are submitted herewith. A marked version showing deleted material as crossed out lines and added material as underlining and also a clean version of substitute specification and abstract are submitted herewith.

The substitute specification and abstract contains no new matter. Applicant respectfully requests Examiner to enter substitute specification and abstract.

Claim Objections

Appropriate correction and amendment of all objected claims are done to meet requirements of Examiner. Applicant respectfully request withdrawal of claim objections and allow entry of amended claims.

Claim Rejections - 35 U.S.C. § 112

On page 04-05 of Final Office Action mailed on March, 15, 2010, the Examiner rejected Claims **13,14 and 17** under 35 U.S.C. § 112, first paragraph. The Examiner is thanked for continuing examination, and thereby furthering prosecution. Applicant has amended claims to overcome rejection under 35 U.S.C. § 112, first paragraph.

Applicant respectfully requests to withdraw rejection of claims 13, 14 and 17 under 35 U.S.C. § 112, first paragraph and allow entry of these claims.

Claim Rejections - 35 U.S.C. § 102

On page 5-6 of the Outstanding Office Action **Claim 13-15** were rejected under **35 U.S.C. § 102(b)** as being anticipated by "Vicenzi." (US 5,281,225). Applicant respectfully requests entry of amended independent Claim 13 and dependent claims 14-15. Claim 13-15 have been amended to further describe Applicant's invention. Support for such amendments may be found throughout the specification, at, e.g. paragraphs [0001], [0023], [0025], [0026], [0032], [0035], [0039], [0073], [0077], Figs. 4,5,7,8, and 9. Applicant submits that "Vicenzi." (US 5,281,225) do not suggest or teach or disclose each and every feature or element of amended claim 13-15. For Example-

1. "Vicenzi" does not teach or suggest Intramedullary Pin 1 of *universal length*.

Applicant respectfully request to examiner to read specification of Vicenzi at Col. 1 lines 43-49:

"Within the scope of this technical aim, an object of the present invention is to provide a pin which can be installed with a set of instruments which is extremely simple, is inexpensive and adapts to various dimensional situations of the bone in which it is installed, so that a very small number of sizes is sufficient to satisfy any requirement". Vicenzi teaches to have small number of sizes for various dimensions of bone, so Vicenzi Intramedullary pin 1 will not be possible to be of universal length.

Vicenzi further teaches at Col 2. Lines 37-46:

"At the other end, the stub has at least two (five in the particular illustrated case) elastically deformable curved stems 8 (advantageously made of biocompatible steel such as for example AISI 31 6L) rigidly associated therewith; said stems can have a circular cross section and rounded ends 9; advantageously, one of the stems, for example the central one, is slightly longer than the others so as to define, when the stems are gathered in a bundle, a pointed assembly free end 1a which is easier to orientate and insert in bone cavities."

Vicenzi further teaches in Claim 5. Col.4 Lines 56-57:

"Pin according to claim 1, wherein said stems have rounded ends and one of said stems is slightly longer."

As Vicenzi teaches that stems 8 are rigidly attached with proximal stub 2, free ends 9 of stems 8 are bundled by passing retention metallic wire 11 making loop 14 engaged in groove 15 proximate to ends of stems 8, where one of stems is longer than other stems to define free end 1a of assembly, Intramedullary pin 1 and stems 8 have to be of different length for different group of patient size and bone. As stems 8 are rigidly attached at one end with proximal stub 2 and stems are bundled by metallic wire 11 at other end at grooves 15 proximate to ends of stem 8(see Vicenzi Fig 2, Fig. 4 and Fig 8 , Col. 2 lines 60-63) or holes 17 (Col. 3 lines 5-10) to make stems 8 mutually adjacent to one another and requirement of one of stem to be longer than other , with these structure of Intramedullary pin 1 and stems 8 ,it is not possible to have Vicenzi's Intramedullary pin 1 or stem 8 of universal length to satisfy these requirements. Vicenzi does teach and suggest having small number of sizes to satisfy this requirement (Col. 1 lines 43-49).

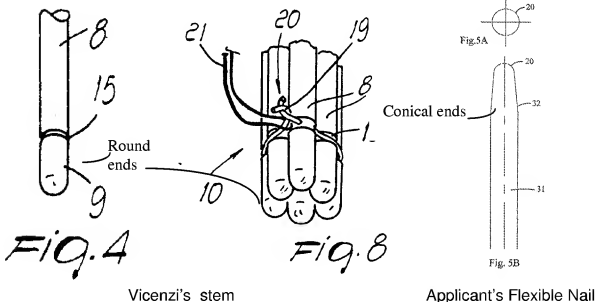
Applicant respectfully disagree with argument of examiner on page no.16-17of

Final Office Action that applicant's same universal length flexible nail can't be used in realistic condition in two different size patient (baby and 6 feet tall man). Applicant respectfully argues that applicant's flexible nail of universal length (for example 50 cm) is free at a first end and also free at a second end and it is not bundled at one end, user (surgeon) is allowed after final insertion to cut nail to size (in fraction of millimeter or centimeter) of bone of a baby or tall man keeping 1 cm out protruding from an entry in a bone. When a surgeon takes a person for surgery of fixing a bone with flexible nail having curvatures in particular can't decide exact and effective length (i.e. extending across the fracture zone, not penetrating inner wall of bone or growth plate at leading end and not irritating soft tissue at non leading end) of nail to be used before hand , so Applicants claims nail of universal length (for example 50 cm) which allows surgeon to effectively extend nail across fracture zone ,after conforming final insertion and placement of leading end to desired position, surgeon will cut non leading end keeping 1cm out protruding - not irritating soft tissue at non leading end. Applicant respectfully argues that flexible nail as claimed by applicant is of universal length for all sizes of bones reducing inventory and allowing surgeon to have effective and exact length of nail for a particular patient and bone. As disclosed and taught by Vicenzi and from above facts applicant respectfully argues that Vicenzi's Pin 1 is no longer in position to meet limitation of universal length and it does not read on claim 13.

2. Structure of Vicenzi Pin 1 requires at least two stems 8 for operation of said Pin 1 (Col 2 lines 37-38 , Col 4 Claim 1 lines 24-25 ,), while applicant discloses and claims in claim 13 an orthopedic implant flexible intramedullary nail comprising a single flexible nail of universal length. Applicant's implant flexible intramedullary nail can operate having structurally a single flexible nail of universal length having a plurality of curvatures at a plurality of planes, while to operate Vicenzi's Pin 1 it requires to have structure of at least two stems 8 in intramedullary Pin 1 to fix a fracture in a bone. So structurally Vicenzi's Pin 1 is different than applicant's implant flexible intramedullary nail.
3. Structure of Vicenzi's Pin 1 requires stem 8 at one end to be rigidly associated or connected with proximal stub 2, (Col 4 Claim 1), while Applicant discloses and claims structure of a flexible nail where first and second ends are free without any attachment. So structurally Vicenzi's Pin 1 is different than applicant's implant flexible intramedullary nail.

4. Applicant discloses and claims structure of flexible nail having a plurality of curvatures at a plurality of planes allowing surgeon to fix , reposition and maintain relation of fragments of fractured bone at multiple contact points of fixation , intramedullary pin 1 disclosed and claimed by Vicenzi does not show such structural limitation.
5. Structure of Vicenzi's intramedullary pin 1 as disclosed and claimed shows that stems 8 are rigidly attached at proximal stub 2, not giving freedom to surgeon to allow each of stem to be repositioned individually freely in relation to each another stem , thereby not allowing freely to reposition and maintain relation of fragments of fractured bone in a desired position to prevent mal union of fracture . Applicant discloses and claims structure of flexible nail where both ends are free without any attachment giving freedom to surgeon to allow each of flexible nail to be repositioned individually freely in relation to each another flexible nail , thereby allowing freely to reposition and maintain relation of fragments of fractured bone in a desired position to prevent mal union of fracture .
6. Applicant discloses and claims structure of flexible nail having a uniform surface along whole length of nail. Vicenzi discloses and claims structure of intramedullary pin 1 where stems 8 are having either grooves 15 proximate to end 9 (see Vicenzi Fig 2, Fig. 4 and Fig 8 emphasis added) or having holes 17 for wire 11 (Col 2; lines 60-63 , Col. 3 ; lines 5-10 , Col 4; Claim 2 lines 43-48, Col 4; Claim 6 lines 59-64)) to keep stems 8 mutually adjacent to make bundle of stems. Surface of stem is not uniform at grooves 15 or holes 17 and structurally this creates a zone of transition leading weakness of stems .Stems break at junction of surface of shaft and surface at groove 15 or holes 17. Applicant respectfully disagree with examiner mentioning that alleged difficulty of insertion of bundled stems and difficulty in unbundling stems within a medullary canal of bone are merely speculations by Applicant. Applicant respectfully argues that It is not mere speculation by Applicant, it has been well documented in orthopedic literature that Vicenzi's bundled nail required opening of fracture zone due to difficulty in negotiating bundled end in opposite fracture fragment without opening the fracture zone (close reduction of fracture fragments tried and failed due to bundle) in majority of cases (81%) and also reported complication of breakage of distal end of nails probably from grooves and mal union of fractures leading users to stop use of such structured nails.

7. Structure of Vicenzi's intramedullary pin 1 as disclosed and claimed shows that stems 8 are having ends 9 rounded. (see Vicenzi Fig. 4, Fig 8 emphasis added) Applicant discloses and claims flexible nail having a first cross section diameter at a shaft and a second diameter at both free ends, wherein second diameter is smaller than first diameter thereby making structure of both free ends conical pathfinder. (Present applicant's application See Fig 5A, 5B emphasis added). So structurally Vicenzi's Pin 1 is different than applicant's implant flexible intramedullary nail.



8. Structure of Vicenzi's intramedullary pin 1 as disclosed and claimed shows that deformable stems 8 are rigidly attached with proximal stub 2 and structure of whole pin 1 is not flexible enough and Vicenzi does not teach, suggest or motivate to have structural property of stem 8 or stub 2 having percentage of elongation 15-25% to allow a plurality of curvatures at a plurality of planes to

fix, reposition and maintain relation of fragments of fractured bone and prevent mal relation of fractured bone fragments. Mal relation of fragments after using flexible nails is known in art. Inventor applicant has done series of experiments and observations with prior art flexible nails and found out problem of mal relation of fracture fragments after using flexible nails in prior art. Inventor applicant found that problem is due to structural property of prior art flexible nails having percentage of elongation on tensile stress substantially lower than 15% irrespective to material from which these flexible nails manufactured.(for example , 316 L stainless steel, Titanium Alloys or other biocompatible material) . Applicant reduced to practice invention and found that structural property of flexible nail having 15-25% percentage of elongation on tensile stress has solved the problem of mal relation of fragments of fractured bone irrespective of material from which nails manufactured. Vicenzi does not disclose problem in prior art of difficulty in maintaining relation of fragments of and also does not recognize the reason for the problem and so does not offer solution to particular problem or it does not teach, or suggest or motivate one of ordinary skill in art to have percentage of elongation 15%-25% as structural limitation in Intramedullary pin 1. Vicenzi provides structure of intramedullary pin 1 such that it primarily focuses and objects to eliminate need of lock distal ends of routine nailing generally in adults to obviate need for intra operative imaging leading to exposure to surgeon , assistant and staff to ionizing radiation by providing self locking metaphyseal pin . (Vicenzi Col.1 lines 5-27). Applicant respectfully disagree to observation of examiner that as Vicenzi pin is made from 36 Stainless Steel , so it has structural limitation of 15-25% elongation on tensile stress .With the support of factual arguments as stated above, Applicant respectfully further argues that applicant has found out one of the reasons for the problem in prior art of malrelation of fragment and that is due to low flexibility of prior art nails and has described in specification to have higher flexibility with structural property of flexible nail having 15%-25% of elongation of nail on tensile stress as solution to such problem as described in various paragraphs of description.

Vicenzi's Nail is *structurally* and *functionally* different than Applicant's disclosure. Accordingly, Vicenzi *does not teach or describe, expressly or inherently, each and every element* as set forth in amended claims 13-16 nor does Vicenzi *have elements arranged as required* by these amended claims 13-16. As such, Vicenzi *does not anticipate or render obvious independent claim 13 or dependent claims 14-16.* Applicant respectfully requests entry and allowance of Claims 13-16.

Claim Rejections Under 35 U.S.C. § 103

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Vicenzi (US 5,281,225 A) in view of Walker (US 4,457,301 A).

Claims 17-19 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vicenzi (US 5,281,225 A) in view of Walker (US 4,457,301 A) and Ender (US 4,467,793 A).

Claims 17 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vicenzi (US 5,281,225 A) in view of Walker (US 4,457,301 A), Haas (US 5,976,140 A), and Grotz (US 5,968,078 A).

Claims 24, 25, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walker (US 4,457,301 A) in view of Haas (US 5,976,140 A) and Grotz (US 5,968,078 A).

Applicant respectfully requests entry of amended Claims 16 -18 and 20-22 and new claims 30-37. Claims amended to further describe Applicant's invention. Support for such amendments may be found throughout the specification, at, e.g., paragraphs [[0001],[0023],[0025],[0026],[0031],[0032],[0035],[0038][0039],[0073],[0075],[0077], **Figs. 4,5,7,8,9,11A,11B,12A,12B,13, 14, 15,16,17,18 and 19.** New claims believed not to add new matter. Without acquiescing to any of the contentions in the Outstanding Office Action, it is respectfully asserted that the according to amended claim 17 and other claims, present invention *as a whole* is constructed structurally different from device of Vicenzi and device of Walker and is used in an entirely different manner, thereby overcoming drawbacks in the apparatus of Vicenzi and apparatus and method of Walker individually or combined, as well as many similar devices known in the prior art of record.

For example

1. "Vicenzi" does not teach or suggest Intramedullary Pin 1 of *universal length*.

Applicant respectfully request to examiner to read specification of Vicenzi at Col. 1 lines 43-49:

"Within the scope of this technical aim, an object of the present invention is to provide a pin which can be installed with a set of instruments which is extremely simple, is inexpensive and adapts to various dimensional situations of the bone in which it is installed, so that a very small number of sizes is sufficient to

satisfy any requirement". Vicenzi teaches to have small number of sizes for various dimensions of bone, so Vicenzi Intramedullary pin 1 will not be possible to be of universal length.

Vicenzi further teaches at Col 2. Lines 37-46:

"At the other end, the stub has at least two (five in the particular illustrated case) elastically deformable curved stems 8 (advantageously made of biocompatible steel such as for example AISI 31 6L) rigidly associated therewith; said stems can have a circular cross section and rounded ends 9; advantageously, one of the stems, for example the central one, is slightly longer than the others so as to define, when the stems are gathered in a bundle, a pointed assembly free end 1a which is easier to orientate and insert in bone cavities."

Vicenzi further teaches in Claim 5. Col.4 Lines 56-57:

"Pin according to claim 1, wherein said stems have rounded ends and one of said stems is slightly longer."

As Vicenzi teaches that stems 8 are rigidly attached with proximal stub 2, free ends 9 of stems 8 are bundled by passing retention metallic wire 11 making loop 14 engaged in groove 15 proximate to ends of stems 8, where one of stems is longer than other stems to define free end 1a of assembly. Intramedullary pin 1 and stems 8 have to be of different length for different group of patient size and bone. As stems 8 are rigidly attached at one end with proximal stub 2 and stems are bundled by metallic wire 11 at other end at grooves 15 proximate to ends of stem 8(see Vicenzi Fig 2, Fig. 4 and Fig 8 , Col. 2 lines 60-63) or holes 17 (Col. 3 lines 5-10) to make stems 8 mutually adjacent to one another and requirement of one of stem to be longer than other , with these structure of Intramedullary pin 1 and stems 8 ,it is not possible to have Vicenzi's Intramedullary pin 1 or stem 8 of universal length to satisfy these requirements. Vicenzi does teach and suggest having small number of sizes to satisfy this requirement (Col. 1 lines 43-49).

Applicant respectfully disagree with argument of examiner on page no.16-17 of Final Office Action that applicant's same universal length flexible nail can't be used in realistic condition in two different size patient (baby and 6 feet tall man). Applicant respectfully argues that applicant's flexible nail of universal length (for example 50 cm) is free at a first end and also free at a second end and it is not bundled at one end, user (surgeon) is allowed after final insertion to cut nail to size (in fraction of millimeter or centimeter) of bone of a baby or tall man keeping 1 cm out protruding from an entry in a bone. When a surgeon takes a person for

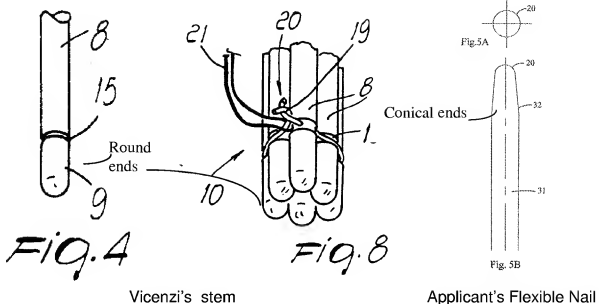
surgery of fixing a bone with flexible nail having curvatures in particular can't decide exact and effective length (i.e. extending across the fracture zone, not penetrating inner wall of bone or growth plate at leading end and not irritating soft tissue at non leading end) of nail to be used before hand , so Applicants claims nail of universal length (for example 50 cm) which allows surgeon to effectively extend nail across fracture zone ,after conforming final insertion and placement of leading end to desired position, surgeon will cut non leading end keeping 1cm out protruding - not irritating soft tissue at non leading end. Applicant respectfully argues that flexible nail as claimed by applicant is of universal length for all sizes of bones reducing inventory and allowing surgeon to have effective and exact length of nail for a particular patient and bone. As disclosed and taught by Vicenzi and from above facts applicant respectfully argues that Vicenzi's Pin 1 is no longer in position to meet limitation of universal length

2. .Structure of Vicenzi's Pin 1 requires stem 8 at one end to be rigidly associated or connected with proximal stub 2, while Applicant discloses and claims structure of flexible nail where first and second ends are free without any attachment. So structurally Vicenzi's Pin 1 is different than applicant's implant flexible intramedullary nail.
3. Applicant discloses and claims structure of flexible nail having a plurality of curvatures at a plurality of planes allowing surgeon to fix , reposition and maintain relation of fragments of fractured bone at multiple contact points of fixation , intramedullary pin 1 disclosed and claimed by Vicenzi does not show such structural limitation.
4. Structure of Vicenzi's intramedullary pin 1 as disclosed and claimed shows that stems 8 are rigidly attached at proximal stub 2, not giving freedom to surgeon to allow each of stem to be repositioned individually freely in relation to each another stem , thereby not allowing freely to reposition and maintain relation of fragments of fractured bone in a desired position to prevent mal union of fracture . Applicant discloses and claims structure of flexible nail where both ends are free without any attachment giving freedom to surgeon to allow each of flexible nail to be repositioned individually freely in relation to each another flexible nail , thereby allowing freely to reposition and maintain relation of fragments of fractured bone in a desired position to prevent mal union of fracture .

5. Applicant discloses and claims structure of flexible nail having a uniform surface along whole length of nail. Vicenzi discloses and claims structure of intramedullary pin 1 where stems 8 are having either grooves 15 proximate to end 9 (see Vicenzi Fig 2, Fig. 4 and Fig 8, Emphasis added) or having holes 17 for wire 11 (Col 2; lines 60-63 , Col. 3 ; lines 5-10 , Col 4; Claim 2 lines 43-48, Col 4; Claim 6 lines 59-64)) to keep stems 8 mutually adjacent to make bundle of stems. Surface of stem is not uniform at grooves 15 or holes 17 and structurally this creates a zone of transition leading weakness of stems .Stems break at junction of surface of shaft and surface at groove 15 or holes 17. Applicant respectfully disagree with examiner mentioning that alleged difficulty of insertion of bundled stems and difficulty in unbundling stems within a medullary canal of bone are merely speculations by Applicant.

Applicant respectfully argues that It is not mere speculation by Applicant, it has been well documented in orthopedic literature that Vicenzi's bundled nail required opening of fracture zone due to difficulty in negotiating bundled end in opposite fracture fragment without opening the fracture zone (close reduction of fracture fragments tried and failed due to bundle) in majority of cases (81%) and also reported complication of breakage of distal end of nails probably from grooves and mal union of fractures leading users to stop use of such structured nails.

6. Structure of Vicenzi's intramedullary pin 1 as disclosed and claimed shows that stems 8 are having ends 9 rounded.(see Vicenzi Fig. 4, Emphasis added) Applicant discloses and claims flexible nail having a first cross section diameter at a shaft and a second diameter at both free ends , wherein second diameter is smaller than first diameter thereby making structure of both free ends conical pathfinder. (Present applicant's application See Fig 5A, 5B, Emphasis added). So structurally Vicenzi's Pin 1 is different than applicant's implant flexible intramedullary nail.



7. Structure of Vicenzi's intramedullary pin 1 as disclosed and claimed shows that deformable stems 8 are rigidly attached with proximal stub 2 and structure of whole pin 1 is not flexible enough and Vicenzi does not teach, suggest or motivate to have structural property of stem 8 or stub 2 having percentage of elongation 15-25% to allow a plurality of curvatures at a plurality of planes to fix, reposition and maintain relation of fragments of fractured bone and prevent mal relation of fractured bone fragments. Mal relation of fragments after using flexible nails is known in art. Inventor applicant has done series of experiments and observations with prior art flexible nails and found out problem of mal relation of fracture fragments after using flexible nails in prior art. Inventor applicant found that problem is due to structural property of prior art flexible nails having percentage of elongation on tensile stress substantially lower than 15% irrespective to material from which these flexible nails manufactured. (for example, 316 L stainless steel, Titanium Alloys or other biocompatible material). Applicant reduced to practice invention and found that structural property of flexible nail having 15-25% percentage of elongation on tensile stress has solved the problem of mal relation of fragments of fractured bone irrespective of material from which nails manufactured. Vicenzi does not disclose problem in prior art of

difficulty in maintaining relation of fragments of and also does not recognize the reason for the problem and so does not offer solution to particular problem or it does not teach, or suggest or motivate one of ordinary skill in art to have percentage of elongation 15%-25% as structural limitation in Intramedullary pin 1. Vicenzi provides structure of intramedullary pin 1 such that it primarily focuses and objects to eliminate need of lock distal ends of routine nailing generally in adults to obviate need for intra operative imaging leading to exposure to surgeon, assistant and staff to ionizing radiation by providing self locking metaphyseal pin. (Vicenzi Col.1 lines 5-27). Applicant respectfully disagree to observation of examiner that as Vicenzi pin is made from 36 Stainless Steel, so it has structural limitation of 15-25% elongation on tensile stress with the support of factual arguments as stated above. Applicant respectfully further argues that applicant has found out one of the reasons for the problem in prior art of malrelation of fragment and that is due to low flexibility of prior art nails and has described in specification to have higher flexibility with structural property of flexible nail having 15%-25% of elongation of nail on tensile stress *as solution* to such problem as described in various paragraphs of description. Applicant respectfully argues that Examiner has possibly *speculated* possibility of this structural limitation of instant amended claim with hindsight of applicant's disclosure itself.

8. Applicant respectfully further argues that "Walker" teaches to have core 13 is made from either *plastic or ultra high molecular weight polyethylene* (Col. 5 ll 20, Col. 6 ll 11-12) and is *flexible relative to pins* 11 (Col 2. ll 6-7) and it *extends across* the fracture zone and *extends along* essentially whole length of pin (Col. 3 ll 48-51, Fig. 1, 2, and 10.). Applicant discloses a *proximal* fixation device which is made from *Stainless Steel Rod* and is *rigid relative to flexible pins* and *does not extend across* the fracture zone (Fig. 11A, 12A, 17, 18 and 19.) and *does not extend along* essentially whole length of flexible pins to have curvatures at different points and in different planes to get multiple contact point fixation inside the medullary canal without disturbing the fracture zone and to have flexible but stable construct. Plastic core 13 relatively flexible to metal pins and metal pins *both extending across fracture zone* as taught by "Walker" *structurally or functionally* will not be able to allow to have a plurality of curvatures at a plurality of planes to get multiple contact points of fixation inside the medullary canal, which is contrary to Applicant's disclosure.
9. Applicant further argues that Plastic core and metal pins as having sliding fit taught by "Walker" will lead to plastic debris or wear at fracture zone due to

friction between different material having different material properties leading to osteolysis – loss of bone at fracture zone which will delay or abort the healing of bone. Applicant claims flexible pins and proximal fixation device made from same material to remove this drawback.

10. As Examiner has suggested to replace Vicenzi's fixation device with Walker's fixation device to arrive at claimed invention by one of the ordinary skill in art Applicant respectfully argues that such combination or replacement does not give any suggestion or motivation to one of the ordinary skill in art to arrive at amended claims 17-20. If as suggested by Examiner one imagine or intends to use Walker's fixation device in place of Vicenzi's fixation device where core 13 is made from either *plastic or ultra high molecular weight polyethylene* (Walker , Col. 5 ll 20, Col. 6 ll 11-12) and is *flexible relative to pins 11* (Walker , Col. 2. ll 6-7) and it *extends across* the fracture zone and *extends along* essentially whole length of pin (Walker ,Col. 3 ll 48-51, Fig. 1, 2, and 10.) wherein plastic core 13 relatively flexible to metal pins and metal pins *both extending across fracture zone* as taught by " Walker" *structurally or functionally* will not be able to allow to have curvatures at different points and planes to get multiple contact points of fixation inside the medullary canal, which is contrary to Applicant's disclosure.
11. Applicant further points out that even with such combination or replacement of parts of cited prior art will not be able to satisfy structural limitation of element of plurality of flexible nails having 15 %-25% elongation on tensile stress.
12. Even if modification of Walker's fixation device is done - plastic flexible core 13 is modified to adapt securely to targeting device and intended for use with such structural limitation , targeting of possible plural holes in such fixation device by targeting device would not be accurate due to very high flexibility of plastic core relative to pins , angles and adjustment with targeting device will change due deflection of plastic core within medullary canal of a bone (for example femur). Examiner is unsure what applicant's above argument means (Final office action page 21.) Applicant respectfully clarify above argument for clarity as follows: For example if one intends to use Walker fixation device having flexible core 13, modified to have secure attachment (threads) to targeting device and such core 13 further modified to have holes in shaft to receive interlocking screws targeted by targeting device which is aligned to target holes in plastic core 13. Now one intends to insert plastic core for example in medullary canal of

femur bone securely attached with targeting device having holes aligned with holes in plastic core 13, due to very high flexibility of plastic core relative to pins, core will deflect within the medullary canal to match shape of medullary canal, leading to loss of alignment of holes in core which was well aligned with holes in targeting device outside medullary canal before insertion. This will lead to inaccuracy and precision is hampered and targeting is not achieved.

As such teachings of Vicenzi or Walker individually or in combination does not provide suggestion or motivation to one of the ordinary skill in art to arrive at claimed *invention as a whole* and thus do not render it obvious. Applicant respectfully requests entry and allowance of Claims 13-18 and 20-22,

Conclusion

Consideration for and allowance of the pending claims in this Application, as provided in the Listing of Claims beginning on page three of this paper are respectfully requested for the reasons set forth herein. In light of amendments, remarks and arguments presented with this paper, Applicant respectfully submit that the pending and amended claims are in condition for allowance. No new matter has been introduced with this Amendment. This amendment is timely filed under CFR 1.116. No additional fees are believed due with this response.

Any remarks in support of patentability of one claim should not be imputed to any other claim, even if similar terminology is used. Any remarks referring to only a portion of a claim should not be understood to base patentability on that portion; rather, patentability must rest on each claim taken as a whole. Applicants respectfully traverse each of the Examiner's rejections and each of the Examiner's assertions regarding what the cited references show or teach, even if not expressly discussed herein. Although changes to the claims have been made, no acquiescence or estoppel is or should be implied thereby; such amendments are made only to expedite prosecution of the present application and are without prejudice to the presentation or assertion, in the future, of claims relating to the same or similar subject matter. If the undersigned has overlooked a relevant teaching in any of the references, the Examiner is requested to point out specifically where such teaching may be found.

If the Examiner has any question or comments or if further clarification is required and if it is believed that an interview might be useful, Applicant respectfully requests examiner to contact the undersigned inventor at the telephone number: +91 9825387016 or indicate such questions or clarifications or requirement to contact.

Date: May 10, 2010
39/B, Hindu colony,
Opp.S.P. Stadium, Navrangpura
Ahmedabad, Gujarat, India
Pin: 380009
Telephone: +91 9825387016
Email: naveenthakkar@gmail.com

Respectfully submitted,
/Navin N Thakkar/
Signature
Printed Name: Navin N. Thakkar
Inventor
Customer Number: 86798